

**GLUMA Desensitizer PowerGel / Heraeus Kulzer, Inc. URGENT SAFETY INFO Update (9/14)**

**Reason/Information:**

Heraeus Kulzer (HKG) issued an Urgent Safety Information on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: Single syringes of these lots show a more than usual jerky extrusion behavior. In one case this led to a fluid ejection from the syringe in front of a hygienist when pushing harder on the plunger rod outside the mouth. This near accident and further complaint reports about the same issue resulted in an evaluation of the paste's properties and primary packaging details. These thorough evaluations make HKG aware that the used primary packaging, namely closing cap and plunger rod, in combination with a more liquid viscosity of the lots of these two syringes may have led to the unwanted behavior as described above.

If uncontrolled fluid ejection from the syringe occurs, the dental patient especially could be exposed to the gel reaching the mucosa, the face, or even the eyes causing irritation, chemical burns and blistering of the tissues, which is a medically reversible condition. This could happen to the users and any involved third person too, when safety hints and precautions for use of the selected product are disregarded.

A serious injury may occur and cannot be excluded completely by the product warnings and the safety precautions (such as the use of safety glasses and rubber dam during treatment as indicated in the Instructions for Use). In the best interest of HKG customer's safety, HKG is voluntarily recalling this product to keep the risk of occurrence to a minimum. Up to now, HKG has not received any reports on incidents or a serious injury of a patient. Nevertheless, as a responsible manufacturer of high quality medical devices, HKG has decided to minimize any risk and to immediately recall the concerned lots of these syringes. This is a prophylactic preventive action.

**Disposition/Instructions:**

Search the inventory and immediately remove any affected lots of GLUMA Desensitizer PowerGel Assortments, or any syringe samples with affected lots.

Send all identified products to the customer's dealer or directly to HKG's address; Heraeus Kulzer GmbH, Alte Heersstrabe, Geb. B802, 41538 Dormagen, Germany.

Copy the delivery note of the customer's return shipment to the customer's dealer for replacement or credit. The replacement or credit can only be issued by the entity where the customer originally bought the product.

Dealers must identify any customers that the mentioned lots of GLUMA Desensitizer PowerGel were distributed to. Identify each customer by name, phone number, and address. Since the customer distributes this product to end users, customers must contact each one of their customers. Instruct customers to cease usage of these particular lots with this Urgent Safety Information and return the product to HKG either via the customer's organization or directly to the address of HKG listed above.

If the customers are end-users of the product, identify any GLUMA Desensitizer PowerGel with the aforementioned lots or any syringe samples in the customer's surgery or clinic rooms with the noted lots. If the customer identifies any product, cease usage and send products to the customer's dealer or directly to the address of HKG.

If the customer of a dental material supplier has forwarded this product to any other end users, identify each customer by name, phone number, and address.

Return the affected materiel to the customer's local HKG sales organization.

Call HKG at 914-219-9000 or 914-273-8600 for address to send affected materiel.

Item Information:

NSN (FSC-NIIN): 6515-NS  
Part Number: 66043451  
Nomenclature: GLUMA DESENSITIZER POWERGEL  
UI: EA  
Manufacturer: HERAEUS KULZER INC

LOT / SN:  
010103  
10104

**NOTES:**

NOTE 1:

Lot #010103 - Expiration Date - September 2015; Lot #10104 - Expiration Date - June 2016

NSN (FSC-NIIN): 6515-NS  
Nomenclature: POWERGEL SYRINGES CONTAINED IN THE FOLLOWING KIT  
UI: EA  
Manufacturer: HERAEUS KULZER INC

LOT / SN:  
42  
43 44 45  
46 47 48 49  
50 51

NOTES:

NOTE 1:

All Lot numbers expiration date - September 2015

NSN (FSC-NIIN): 6515-NS  
Part Number: 66052803  
Nomenclature: GLUMA DESENSITIZER POWERGEL  
UI: EA  
Manufacturer: HERAEUS KULZER INC

LOT / SN:  
010103

10104

NOTES:

NOTE 1:

Lot #010103 - Expiration Date - September 2015; Lot #10104 - Expiration Date - June 2016

POC Contact Information:

USAMMC-E

Email: [usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil](mailto:usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil)

Phone (COMM): 011-49-6331-86-7118/7181

Phone (DSN): 495-7118

Fax: 6218

US ARMY

Email: [usarmy.detrick.medcom-usamma.mbx.doc@mail.mil](mailto:usarmy.detrick.medcom-usamma.mbx.doc@mail.mil)

Phone (COMM): 301-619-4300

Phone (DSN): 343-4300

Fax: 301-619-4468

US AIR FORCE

Email: [afmoa.sgalc@us.af.mil](mailto:afmoa.sgalc@us.af.mil)

Phone (COMM): 301-619-4170

Phone (DSN): 343-4170

Fax: 301-619-2557

US NAVY

Email: [MMQC2@MED.NAVY.MIL](mailto:MMQC2@MED.NAVY.MIL)

Phone (COMM): 301-619-3085

Phone (DSN): 343-3085

Fax: 301-619-2473

Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In Afi 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

Additional Documentation located [here](#).